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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,522	05/02/2005	Istvan Hudak	9007-1011	1625

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YOUNG & THOMPSON
745 SOUTH 23RD STREET
2ND FLOOR
ARLINGTON, VA 22202

EXAMINER
ROGERS, JAMES WILLIAM

ART UNIT	PAPER NUMBER
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/533,522	HUDAK, ISTVAN	
	Examiner	Art Unit	
	James W. Rogers, Ph.D.	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05/09/2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendments to the claims filed 05/07/2007 have been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 43 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically claim 43recties that the auxiliaries can be selected from the group at lines 3-5 and mixtures thereof. There is no written support within the specification that the auxiliaries listed may be present in mixtures with one another.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 32-36,40-41,43,45-50,54-55 and 57-58 are rejected under 35 U.S.C. 102(b) as being anticipated by Garibaldi (US 6,296,604 B1, cited by applicants

and in last office action), a new reasoning for the rejection of claim 58 was necessitated by amendment.

Garibaldi teaches a biocompatible composition comprised of a precipitating polymer such as polyurethane, an adhesive and a magnetic embolic agent (including barium or tantalum), the polyurethane was dissolved in a biocompatible solvent such as DMSO and EtOH. See col 2 lin 63-col 3 lin 7, lin 53-62, col 4 lin 13-23 and claims 1-9 and 14. Regarding the limitation that the composition is used to fill or short-circuit a vascular cavity, Garibaldi teaches several uses for the composition to treat vascular defects including covering aneurisms and covering injured sections on the inside of a vessel, thus meeting the limitation of filling a vascular cavity. See col 8 lin 10-54. Regarding the limitations on the viscosity of the composition Garibaldi claims a viscosity between about 30 and about 1500 centipoise within applicants specified range, the examiner assumes the viscosity measurements would be conducted at room temperature. Regarding new claim 58 Garibaldi specifically mentions that the compositions are delivered by catheter.

Response to Arguments

Applicant's arguments filed 05/18/2007 have been fully considered but they are not persuasive.

Applicants assert that there is no suggestion or hint in Garibaldi of using polyurethane or the amount of polyurethane to fill or short circuit a vessel and there is no recognition of using solvent or the amount of solvent as claimed. Applicants assert that Garibaldi teaches using the solvents and biopolymers “sparingly”.

The relevance of these assertions is unclear. Clearly Garibaldi teaches a composition to fill or short circuit a vascular cavity, the composition was successful in its intended use therefore the amount of biopolymer (including polyurethane) and solvent were sufficient for the recited use. For the claims rejected by Garibaldi applicants have not claimed anything in particular that is patentably distinct from Garibaldi, there is no recitation of a distinct amount of biopolymer or solvent, only a recitation that the solvent dissolves the polymer (which Garabaldi teaches) and the amount of polyurethane is sufficient to fill a vascular cavity. Lastly as far as Garbaldi teaching sparing use of the polyurethane and solvent, since the composition performs its intended duty one again the amount of polymer and solvent were sufficient to fill a vascular cavity. Also it appears as though applicants may be trying to show that Garbaldi teaches away from their claimed invention, since the Garibaldi patent was used in a 102(b) type of rejection this type of argument is moot.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 32-34,37-42,44,46-48 and 51-56 are rejected under 35 U.S.C. 102(b) as being anticipated by Marinovic (EP 0 280,451, cited by applicants and in last action), this new reasoning for a rejection was necessitated by amendment.

Marinovic teaches polyurethanes prepared by mixing prepolymers of diisocyanate (including MDI) and polyols such as polypropylene glycol, the polyurethanes were useful as space filling adhesive sealants in surgery. See abstract, page 3 lin 14-58, page 4 lin 6-58 and page 6 lin 11-36. Regarding claims 32 and 46 the intended use of the composition for filling or short circuiting vascular cavities was given no patentable weight by the examiner because the claims are drawn to a method of preparing a composition or a kit or the claims are drawn to a composition or a kit. "Where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation"); Kropa v. Robie, 187 F.2d at 152, 88 USPQ2d at 480-81. The polyurethanes within Marinovic could be used in a package containing separate compartments for the polymer and an aqueous solution containing a chain extender (meets limitation of usual auxiliary and solvent), the polymer and aqueous solution are conveniently mixed prior to use as space filling tissue adhesives. See claims 12-16. Regarding the limitations regarding MW of the polyurethane, Marinovac teaches that the polyglycol has an average MW of 650-5000 and the diisocyanate/polyglycol monomers are in a 2:1 ratio, therefore the MW of the entire polymer would be between 1,950-15,000, within applicants specified range. Regarding the limitation that the diol component is HO-R'-OH, where R' stands for a C1-C8 alkylene group, polypropylene glycol is formed by a condensation of the C3 diol propylene glycol, as evidenced by applicants own specification polypropylene glycol is a special sub-group of diols and

therefore meets applicants limitation above. See [0072] in US 2006/0008499 A1 patent application publication of 10/533,522.

Response to Arguments

Applicant's arguments filed 05/18/2007 have been fully considered but they are not persuasive.

Applicants assert that the polyurethane is only a starting material in the preparation of a final crosslinked polyurethane polymer applied in the human body and does not coincide with the claimed combination.

The relevance of this assertion is unclear. Firstly as currently amended applicants claimed invention does not preclude the use of a crosslinked or chain-extended polyurethane as disclosed within Marinovic, because the transitional phrase the transitional term "comprising", which is synonymous with "including", "containing", or "characterized by", is inclusive or open ended and does not exclude additional elements or method steps recited in the prior art. Invitrogen Corp. v. Biocrest Mfg., L.P., 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003). Secondly a prepolymer solution can still read on applicants claimed invention because as disclosed above the intended use of the composition was given no patentable weight, therefore any composition that meets applicants claimed composition will be able to perform that function.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

> invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 32-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garibaldi (US 6,296,604 B1, cited by applicants) in view of Marinovic (EP 0 280,451, cited by applicants).

Garibaldi is disclosed above. While Garibaldi discloses the use of polyurethanes the patent does not detail the exact diisocyanate and polyol monomers that were used to produce the polymer and the patent is silent on the MW of the polyurethanes.

Marinovic is disclosed above.

Marinovic is used to primarily show that polyurethanes within applicants claimed MW range and formed by the condensation products of the specific diisocyanates and polyols as currently claimed by applicant was already known to be used as an adhesive sealant in surgery The advantages of the disclosed adhesives within Marinovic is its application as a viscous liquid which can be sculpted, once in place the adhesive is rubbery and not brittle or subject to shattering and the adhesive is non-toxic.

It would have been prime facie obvious to a person of ordinary skill in the art at the time the claimed invention was made to combine the art described in the documents above because Garibaldi discloses all of applicants claimed invention but is silent on the monomers used to produce the polymer and the polymers molecular weight while Marinovic discloses that polyurethanes within applicants claimed MW range and formed by the condensation products of the specific diisocyanates and polyols as claimed was already known to be used as an adhesive sealant in surgery. The motivation to combine the above documents would be to produce a composition comprised of a polyurethane

an auxiliary and solvent useful for filling vascular cavities. The advantage of the disclosed composition with a polyurethane within a specific MW and produced by the condensation of specific monomers such as MDI and C1-C8 diols would be that the polyurethane would have a desirable viscosity which is rubbery when applied and not brittle and is non-toxic all of which are obviously desirable traits in surgical adhesives. Thus, the claimed invention, taken as a whole was *prima facie* obvious over the combined teachings of the prior art.

Response to Arguments

Applicant's arguments filed 05/18/2007 have been fully considered but they are not persuasive.

Applicants assert that Garibaldi does not disclose the use of polyurethane without the use of further material to facilitate binding of the polyurethane to the vascular cavity. Applicants also assert that Garibaldi teaches away form their claimed invention because it is disclosed that the amount of polymers and solvents employed may be limited due to incorporation of a magnetic object.

The relevance of these assertions is unclear. As already stated above Garibaldi discloses a composition to fill a vascular cavity, the composition was successful in its intended use therefore the amount of biopolymer (including polyurethane) and solvent were sufficient for the recited use therefore the limitations in claims 32 and 46 are met. Garibaldi does not teach away just because the amount of polyurethane and solvent can be lessened by incorporation of the magnetic particles, as stated above the amount

of polyurethane and solvent are sufficient to fill a vascular cavity and applicants claims do not preclude the use of the magnetic objects within Garibaldi.

Applicants assert that Marinovic does not disclose or suggest using polyurethane for filling or short-circuiting vascular cavities. Applicants also assert that Marinovic has a different utility; namely it is used as a space filling adhesive sealant in neurosurgery, otorhinolaryngological surgery and plastic reconstructive surgery. Therefore applicants state one of skill in the art would lack the motivation to combine and modify the publications so as to obtain the claimed invention.

The relevance of these assertions is unclear. Firstly since Markinovic is used as a secondary reference in a 103(a) type of rejection it does not have to meet applicants intended use on its own merit. Secondly while Marinovic's adhesive is used for other uses not disclosed within Garibaldi the two patents are related as pertaining to surgical adhesive sealants that comprise biopolymers, therefore the examiner believes that one of ordinary skill in the art could see that the two references are combinable.

Applicants state that the polyurethane applied in Marinovic cannot be applied by the method of Garibaldi because it does not harden without the use of a further chain extender.

The relevance of this assertion is unclear. The arguments above for Marinovic in regards to this argument are incorporated herein as well. As in the arguments above applicants claimed invention does not preclude further treating the polyurethane so as to obtain a chain extended polyurethane nor does applicants claimed invention preclude the use of a pre-polymer as the polyurethane.

Applicants state that they have found unexpected results in that polyurethane solution can be used without further solid material present to facilitate the binding of the polyurethane to the vascular cavity.

The relevance of this assertion is also unclear. Applicants claims as currently amended do not preclude the use of solid martial which facilitates binding along with polyurethane, therefore the above limitation was not searched by the examiner. As disclosed above the transitional term "comprising", which is synonymous with "including", "containing", or "characterized by", is inclusive or open ended and does not exclude additional elements or method steps recited in the prior art. Invitrogen Corp. v. Biocrest Mfg., L.P., 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003).

Conclusion

No claims are allowed at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP §706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 271-0616. The fax phone number for the organization where this application or proceeding is assigned is 572-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER